



DOCKET NO.: C1037.70045US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Krieg et al.
Serial No.: 10/613,228
Confirmation No.: 4680
Filed: July 3, 2003
For: NUCLEIC ACID COMPOSITIONS FOR STIMULATING IMMUNE RESPONSES
Examiner: Nita M. Minnifield
Art Unit: 1645

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 17th day of November, 2006.

Emily E. Zokauskas
Emily E. Zokauskas

MAIL STOP AMENDMENT
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check in the amount of \$180 is enclosed to cover the filing fee. If the fee is insufficient, the balance may be charged to Deposit Account 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,

By:

Maria A. Trevisan
Maria A. Trevisan, Reg. No.: 48,207
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Docket No.: C1037.70045US00
Date: November 17 2006
xNDDx



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Emily E. Zukauskas
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MAIL STOP AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed more than three months after the filing date of this application and after the mailing date of the first Office action, but before the mailing date of any final action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in this application.

The fee of \$180.00 as set forth in 37 C.F.R. §1.17(p) is enclosed.

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11/21/2006 RBELETE1 00000092 10613228

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180.00 OP

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified PTO/SB/08). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>	<u>Docket No.</u>
11/179,008	07-08-2005	Hartmann et al.	*C1039.70044US02
11/503,377	08-11-2006	Krieg et al.	*C1039.70061US01
11/503,483	08-11-2006	Krieg et al.	*C1039.70048US22
11/507,079	08-18-2006	Krieg et al.	*C1039.70035US04
11/526,197	09-22-2006	Krieg et al.	*C1039.70048US23
11/526,896	09-22-2006	Bratzler et al.	*C1037.70013US03
11/542,845	10-04-2006	Krieg et al.	*C1037.70048US01
11/543,314	10-04-2006	Lipford et al.	*C1041.70036US02

*A copy of this reference is not provided as the Office has waived the requirement under 37 C.F.R. 1.98(a)(2)(iii) for submitting a copy of a cited U.S. patent application if it is scanned to the Image File Wrapper system and is available on Private PAIR.

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 (modified PTO/SB/08) be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;

3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his or her own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

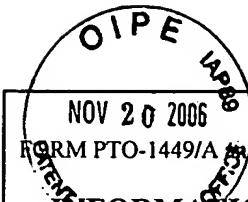
Respectfully submitted,

By:



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Docket No.: C1037.70045US00
Date: November 7, 2006
xNDDx



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FORM PTO-1449/A and B (modified PTO/SB/08)
**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Sheet	1	of	7
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APPLICATION NO.:	10/613,228	ATTY. DOCKET NO.:	C1037.70045US00
FILING DATE:	July 3, 2003	CONFIRMATION NO.:	4680
APPLICANT:	Krieg et al.		
GROUP ART UNIT:	1645	EXAMINER:	Nita M. Minnifield

U.S. PATENT DOCUMENTS

Examiner's Initials #	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A61	6,030,955		Stein et al.	02-29-2000
	A62	6,558,670	B1	Friede et al.	05-06-2003
	A63	6,610,661	B1	Carson et al.	08-26-2003
	A64	6,821,957	B1	Krieg et al.	11-23-2004
	A65	6,943,240		Bauer et al.	09-13-2005
	A66	6,949,520		Hartmann et al.	09-27-2005
	A67	7,001,890		Wagner et al.	02-26-2006
	A68	2002-0192184	A1	Carpentier et al.	12-19-2002
	A69	2004-0038922	A1	Haensler et al.	02-26-2004
	A70	2004-0047869	A1	Garcon et al.	03-11-2004
	A71	2004-0229835	A1	Krieg et al.	11-18-2004
	A72	2004-0234512	A1	Wagner et al.	11-25-2004
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	A74	2004-0235774	A1	Bratzler et al.	11-25-2004
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	A79	2005-0004061	A1	Krieg et al.	01-06-2005
	A80	2005-0004144	A1	Carson et al.	01-06-2005
	A81	2005-0009774	A1	Krieg et al.	01-13-2005
	A82	2005-0013812	A1	Dow et al.	01-20-2005
	A83	2005-0031638	A1	Dalemans et al.	02-10-2005
	A84	2005-0032734	A1	Davis et al.	02-10-2005
	A85	2005-0032736	A1	Krieg et al.	02-10-2005
	A86	2005-0037403	A1	Krieg et al.	02-17-2005
	A87	2005-0037985	A1	Krieg et al.	02-17-2005
	A88	2005-0043529	A1	Davis et al.	02-24-2005
	A89	2005-0049215	A1	Krieg et al.	03-03-2005
	A90	2005-0054601	A1	Wagner et al.	03-10-2005
	A91	2005-0054602	A1	Krieg et al.	03-10-2005
	A92	2005-0059619	A1	Krieg et al.	03-17-2005

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.
Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08)			APPLICATION NO.: 10/613,228	ATTY. DOCKET NO.: C1037.70045US00
INFORMATION DISCLOSURE STATEMENT BY APPLICANT			FILING DATE: July 3, 2003	CONFIRMATION NO.: 4680
			APPLICANT: Krieg et al.	
Sheet	2	of	7	GROUP ART UNIT: 1645 EXAMINER: Nita M. Minnifield

A93	2005-0059625	A1	Krieg et al.	03-17-2005
A94	2005-0064401	A1	Olek et al.	03-24-2005
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A106	2005-0215500	A1	Krieg et al.	09-29-2005
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A123	2006-0003955	A1	Krieg et al.	01-05-2006
A124	2006-0003962	A1	Ahluwalia et al.	01-05-2006
A125	2006-0019916	A1	Krieg et al.	01-26-2006
A126	2006-0019923	A1	Davis et al.	01-26-2006
A127	2006-0058251	A1	Krieg et al.	03-16-2006
A128	2006-0089326	A1	Krieg et al.	04-27-2006

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			GROUP ART UNIT: 1645	EXAMINER: Nita M. Minnifield
Sheet 3 of 7				

	A129	2006-0094683	A1	Krieg et al.	05-04-2006
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	A133	2006-0188913	A1	Krieg et al.	08-24-2006
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	A136	2006-0229271	A1	Krieg et al.	10-12-2006
	A137	2006-0241076	A1	Uhlmann et al.	10-26-2006
	A138	2006-0246035	A1	Ahluwalia et al.	11-02-2006

FOREIGN PATENT DOCUMENTS

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			
	B6	EP	0 302 758	A1	New England Medical Center Hospitals, Inc.	02-08-1989	
	B7	EP	0 468 520	A2	Mitsui Toatsu Chemicals, Inc.	01-29-1992	
	B8	WO	96/02555	A1	University of Iowa Research Foundation	02-01-1996	
	B9	WO	99/56755	A1	University of Iowa Research Foundation	11-11-1999	
	B10	WO	00/06588	A1	University of Iowa Research Foundation	02-10-2000	
	B11	WO	00/15256	A2	Pasteur Merieux Serums Et Vaccins [FR]	03-23-2000	Abstract
	B12	WO	00/54803	A2	Panacea Pharmaceuticals, LLC.	09-21-2000	
	B13	WO	00/61151	A2	The Government of the United States of America	10-19-2000	
	B14	WO	00/67787	A2	The Immune Response Corporation	11-16-2000	
	B15	WO	01/35991	A2	Dynavax Technologies Corporation	05-25-2001	
	B16	WO	01/45750	A1	Regents of the University of California	06-28-2001	
	B17	WO	02/28428	A2	Aventis Pasteur [FR]	04-11-2002	Abstract
	B18	WO	2004/007743	A2	Coley Pharmaceutical GmbH	01-22-2004	
	B19	WO	2004/026888	A2	Coley Pharmaceutical GmbH	04-01-2004	
	B20	WO	2004/094671	A2	Coley Pharmaceutical GmbH	11-04-2004	
	B21	WO	2005/004910	A2	Intercell Ag	01-20-2005	
	B22	WO	2005/023289	A1	Intellectual Property Consulting Incorporated	03-17-2005	Abstract

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Sheet	4	of	7	GROUP ART UNIT: 1645	EXAMINER: Nita M. Minnifield

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C1	ASKEW et al., CpG DNA induces maturation of dendritic cells with distinct effects on nascent and recycling MHC-II antigen-processing mechanisms. <i>J Immunol.</i> 2000 Dec 15;165(12):6889-95.	
	C2	AUF et al., Implication of macrophages in tumor rejection induced by CpG-oligodeoxynucleotides without antigen. <i>Clin Cancer Res.</i> 2001 Nov;7(11):3540-3.	
	C3	BARAL et al., Immunostimulatory CpG oligonucleotides enhance the immune response of anti-idiotype vaccine that mimics carcinoembryonic antigen. <i>Cancer Immunol Immunother.</i> 2003 May;52(5):317-27.	
	C4	BLAZAR et al., Synthetic unmethylated cytosine-phosphate-guanosine oligodeoxynucleotides are potent stimulators of antileukemia responses in naive and bone marrow transplant recipients. <i>Blood.</i> 2001 Aug 15;98(4):1217-25.	
	C5	BROIDE et al., DNA-Based immunization for asthma. <i>Int Arch Allergy Immunol.</i> 1999 Feb-Apr;118(2-4):453-6.	
	C6	BRUNNER et al., Enhanced dendritic cell maturation by TNF-alpha or cytidine-phosphate-guanosine DNA drives T cell activation in vitro and therapeutic anti-tumor immune responses in vivo. <i>J Immunol.</i> 2000 Dec 1;165(11):6278-86.	
	C7	CARPENTIER et al., Successful treatment of intracranial gliomas in rat by oligodeoxynucleotides containing CpG motifs. <i>Clin Cancer Res.</i> 2000 Jun;6(6):2469-73.	
	C8	CARPENTIER et al., Oligodeoxynucleotides containing CpG motifs can induce rejection of a neuroblastoma in mice. <i>Cancer Res.</i> 1999 Nov 1;59(21):5429-32.	
	C9	CHOI et al., The level of protection against rotavirus shedding in mice following immunization with a chimeric VP6 protein is dependent on the route and the coadministered adjuvant. <i>Vaccine.</i> 2002 Mar 15;20(13-14):1733-40.	
	C10	CHU et al., CpG oligodeoxynucleotides act as adjuvants that switch on T helper 1 (Th1) immunity. <i>J Exp Med.</i> 1997 Nov 17;186(10):1623-31.	
	C11	COOPER et al., Safety and immunogenicity of CPG 7909 injection as an adjuvant to Fluarix influenza vaccine. <i>Vaccine.</i> 2004 Aug 13;22(23-24):3136-43.	
	C12	DAFTARIAN et al., Two distinct pathways of immuno-modulation improve potency of p53 immunization in rejecting established tumors. <i>Cancer Res.</i> 2004 Aug 1;64(15):5407-14.	
	C13	DAVIS et al., CpG ODN is safe and highly effective in humans as adjuvant to HBV vaccine: Preliminary results of Phase I trial with CpG ODN 7909. <i>Third Annual Conference on Vaccine Res.</i> 2000. Abstract s25, number 47.	
	C14	DAVILA et al., Generation of antitumor immunity by cytotoxic T lymphocyte epitope peptide vaccination, CpG-oligodeoxynucleotide adjuvant, and CTLA-4 blockade. <i>Cancer Res.</i> 2003 Jun 15;63(12):3281-8.	
	C15	GALLICHAN et al., Intranasal immunization with CpG oligodeoxynucleotides as an adjuvant dramatically increases IgA and protection against herpes simplex virus-2 in the genital tract. <i>J Immunol.</i> 2001 Mar 1;166(5):3451-7.	
	C16	GAO et al., Bacterial DNA and lipopolysaccharide induce synergistic production of TNF-alpha through a post-transcriptional mechanism. <i>J Immunol.</i> 2001 Jun 1;166(11):6855-60.	

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				APPLICANT: Krieg et al.	
Sheet	5	of	7	GROUP ART UNIT: 1645	EXAMINER: Nita M. Minnifield

C17	GARBI et al., CpG motifs as proinflammatory factors render autochthonous tumors permissive for infiltration and destruction. <i>J Immunol.</i> 2004 May;172(10):5861-9.	
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C26	KATAOKA et al., Antitumor activity of synthetic oligonucleotides with sequences from cDNA encoding proteins of <i>Mycobacterium bovis</i> BCG. <i>Jpn J Cancer Res.</i> 1992 Mar;83(3):244-7.	
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C28	KLINMAN et al., Immunotherapeutic applications of CpG-containing oligodeoxynucleotides. <i>Drug News Perspect.</i> 2000 Jun;13(5):289-96.	
C29	KLINMAN et al., Immune recognition of foreign DNA: a cure for bioterrorism? <i>Immunity.</i> 1999 Aug;11(2):123-9.	
C30	KRIEG et al., Applications of immune stimulatory CpG DNA for antigen-specific and antigen-nonspecific cancer immunotherapy. <i>Eur J Canc.</i> 1999 Oct; 35/Suppl4:S10. Abstract #14.	
C31	KRIEG et al., Enhancing vaccines with immune stimulatory CpG DNA. <i>Curr Opin Mol Ther.</i> 2001 Feb;3(1):15-24.	
C32	KRIEG et al., Bacterial DNA or oligonucleotides containing CpG motifs protect mice from lethal L. monocytogenes challenge. 1996 Meeting on Molecular Approaches to the Control of Infectious Diseases. Cold Spring Harbor Laboratory, September 9-13, 1996: 116.	
C33	KURAMOTO et al., Induction of T-cell-mediated immunity against MethA fibrosarcoma by intratumoral injections of a bacillus Calmette-Guerin nucleic acid fraction. <i>Cancer Immunol Immunother.</i> 1992;34(5):283-8.	
C34	LEE et al., Immuno-stimulatory effects of bacterial-derived plasmids depend on the nature of the antigen in intramuscular DNA inoculations. <i>Immunology.</i> 1998 Jul;94(3):285-9.	
C35	LIU et al., CpG ODN is an effective adjuvant in immunization with tumor antigen. <i>J Invest Med.</i> 1997 Sept;45(7):333A.	

EXAMINER:	DATE CONSIDERED:
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				APPLICANT: Krieg et al.	
Sheet	6	of	7	GROUP ART UNIT: 1645	EXAMINER: Nita M. Minnifield

C36	LONSDORF et al., Intratumor CpG-oligodeoxynucleotide injection induces protective antitumor T cell immunity. <i>J Immunol.</i> 2003 Oct 15;171(8):3941-6.	
C37	MANEGOLD et al., Addition of PF-3512676 (CpG 7909) to a taxane/platinum regimen for first-line treatment of unresectable non-small cell lung cancer (NSCLC) improves objective response—Phase II clinical trial. Pfizer Poster. 2005. Abstract 1131.	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				FILING DATE: July 3, 2003	CONFIRMATION NO.: 4680
				APPLICANT: Krieg et al.	
Sheet	7	of	7	GROUP ART UNIT: 1645	EXAMINER: Nita M. Minnifield

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